

<b>Notice of Allowability</b>	Application No.	Applicant(s)	
	10/027,350	HULTGREN ET AL.	
	Examiner	Art Unit	
	Khatol S Shannan-Shah	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments of 8/10/04.
2. ☒ The allowed claim(s) is/are 1-4, 10-18, 25-32, 53, 59, 61 and 64 renumbered 1-25 respectively.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>11/7/04</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                        |
|   | 9. <input type="checkbox"/> Other _____   |

**Attachment to the Notice of Allowance**

1. Applicants' amendments and response of 4/19/2004 and 7/29/2004 are acknowledged. Claims 5-9, 19 and 54 have been canceled. Claims 1, 10-15, 25, 53, 59, 61 and 64 have been amended. Specification pages 8 and 28 has been amended.
2. Claims 1-4, 10-18, 20-53 and 55-65 are pending in this application. Claims 20-24, 33-52, 55-58, 60, 62, 63 and 65 are withdrawn from further consideration as being drawn to non-elected inventions.
3. Note: Status of claims 53 and 59 should recite, "currently amended" in the listing of the claims, because these claims have been amended. They are incorrectly listed as "original". However, to expedite the prosecution of this application the examiner is assuming the listing of said claims as "amended".

***Examiner's Amendment***

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Alan J. Grant (reg # 33,389) on 11/07/2004. Claims 20-24, 33-52, 55-58, 60, 62, 63 and 65 are canceled (see interview summary).

Please cancel claims 20-24, 33-52, 55-58, 60, 62, 63 and 65.

5. Claims 1-4, 10-18, 25-32, 53, 59, 61 and 64 are under consideration.

***Objections Withdrawn***

6. Objection to the specification made in paragraph 5 of the office action mailed 1/12/2004 is withdrawn in view of applicants' amendments.

***Rejections Moot***

7. Rejections of claims 5-9, 19 and 54 under 35 U.S.C. 112, first paragraph made in paragraphs 7 and 8 of the office action mailed 1/12/2004 is moot in view of cancellation of said claims.

8. Rejections of claims 5-9, 19 and 54 under 35 U.S.C. 112, second paragraph made in paragraph 10 of the office action mailed 1/12/2004 is moot in view of cancellation of said claims.

9. Rejections of claims 5-9, under 35 U.S.C. 102(b), made in paragraph 12 of the office action mailed 1/12/2004 is moot in view of cancellation of said claims.

10. Rejections of claims 5-9, under 35 U.S.C. 102(b), made in paragraph 13 of the office action mailed 1/12/2004 is moot in view of cancellation of said claims.

11. Rejections of claims 5-9, 19 and 54 under 35 U.S.C. 102(b), made in paragraph 14 of the office action mailed 1/12/2004 is moot in view of cancellation of said claims.

***Rejections Withdrawn***

12. Rejection of claim 1-4, 10-18, 25-32, 53, 61 and 64 under 35 U.S.C. 112, first paragraph made in paragraph 8 of the office action mailed 1/12/2004 is withdrawn in view of applicants' amendments.

13. Rejection of claim 1-4, 10-18, 25-32, 53, 61 and 64 under 35 U.S.C. 112, second paragraph made in paragraph 10 of the office action mailed 1/12/2004 is withdrawn in view of applicants' amendments.

Art Unit: 1645

14. Rejections of claim 1-4, and 25-32 under 35 U.S.C. 102(b), made in paragraph 12 of the office action mailed 1/12/2004 is withdrawn in view of applicants' amendments.

15. Rejections of claim 1-4, and 25-32 under 35 U.S.C. 102(b), made in paragraph 13 of the office action mailed 1/12/2004 is withdrawn in view of applicants' amendments.

16. Rejections of claim 1-4, 10-18, 25-32 and 53 under 35 U.S.C. 102(b), made in paragraph 14 of the office action mailed 1/12/2004 is withdrawn in view of applicants' amendments.

***Allowable Subject Matter***

17. Claims 1-4, 10-18, 25-32, 53, 59, 61 and 64 are allowed. Claims are renumbered 1-25 respectively.

The following is an examiner's statement of reasons for allowance:

Claims are drawn to an isolated protein construct comprising a donor-strand complemented pilus protein linked to an effector wherein said donor-strand complemented pilus protein comprises a single donor-strand complemented pilus protein, including active fragments thereof, wherein said active fragment is structurally-stabilized by the presence of a donor strand and wherein said donor-strand complemented pilus protein is not attached to a bacterial cell and wherein said effector does not comprise all or part of either a bacterial pilus-protein or bacterial chaperone.

The prior art fails to anticipate or make obvious the particular protein construct recited in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

Art Unit: 1645

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Rejoinder of Withdrawn Claims**

18. The examiner has reviewed withdrawn claims for possible rejoinder. The withdrawn claims were not rejoined with the allowed claims because the withdrawn process claims are not commensurate in scope with the allowed product claims.

### ***Drawings***

19. The application having been allowed, formal drawings are required in response to this Office Action.

### ***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1645

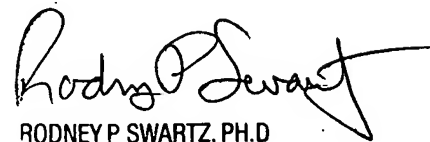
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

November 9, 2004



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER